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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,965	02/02/2004	Yuji Nakajima	040040	4559
23850 7590 07/12/2007 KRATZ, QUINTOS & HANSON, LLP 1420 K Street, N.W. Suite 400 WASHINGTON, DC 20005			EXAMINER ROONEY, NORA MAUREEN	
			ART UNIT 1644	PAPER NUMBER
			MAIL DATE 07/12/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/768,965

Applicant(s)

NAKAJIMA ET AL.

Examiner

Nora M. Rooney

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3,4,6 and 9-30 is/are pending in the application.
- 4a) Of the above claim(s) 9-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-4 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 05/21/2007 is acknowledged.
2. Claims 3-4, 6 and 9-30 are pending.
3. Claims 9-30 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
4. Claims 3-4 and 6 are under examination as they read on an allergen inactivating method.
5. In view of the amendment filed on 05/21/2007, only the following rejection are maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 3-4 and 6 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an allergen inactivating method for the Cryj-2 and Cryj-1 cedar antigens and dust mite extract-Df allergens by maintaining the cedar antigen and dust mites

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allergens under a condition in which any one selected from the group consisting of heat at 80°C, sodium hydroxide, hydrochloric acid and pfu or papain enzymes exists, does not reasonably provide enablement for: **An allergen** inactivating method for dust mites or pollen mainly composed of protein allergens by maintaining **the allergens** under a condition in which the enzyme and a **denaturing agent** exist of claim 3; wherein the denaturing agent is any one of a surfactant, urea and a salt of claim 4; and wherein the enzyme is a protease of claim 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for same reasons as set forth in the Office Action mailed on 12/19/2006.

Applicant's arguments filed on 05/21/2007 have been fully considered, but are not found persuasive.

Applicant argues that there is support in the specification for the presently claimed method, so the specification of the present application provides sufficient enablement to make and use an inactivating method for any allergen.

It is the Examiner's position that the specification provides support for an allergen inactivating method for the Cryj-2 and Cryj-1 cedar antigens and dust mite extract-Df allergens by maintaining the cedar antigen and dust mite allergens under a condition in which any one selected from the group consisting of heat at 80°C, sodium hydroxide, hydrochloric acid and pfu or papain enzymes exists. The specification does not provide support for the inactivation of any

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other allergen using any other conditions other than those specifically disclosed in the specification. As argued in the Office Action mailed on 12/19/2006, Maleki et al. (PTO-892 mailed on 12/19/2006, Reference U) teaches that the denaturation of allergenic peanut proteins by heat may increase IgE binding. Therefore, it is highly unpredictable whether the denaturation of any given protein will inactivate the protein's allergenicity.

8. Claims 3-4 and 6 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of: an allergen inactivating method for the Cryj-2 and Cryj-1 cedar antigens and dust mite extract-Df allergens by maintaining the cedar antigen and dust mites allergens under a condition in which any one selected from the group consisting of heat at 80°C, sodium hydroxide, hydrochloric acid and pfu or papain enzymes exists

Applicant is not in possession of: **An allergen** inactivating method for dust mites or pollen mainly composed of protein allergens by maintaining **the allergens** under a condition in which the enzyme and a **denaturing agent** exist of claim 3; wherein the denaturing agent is any one of a surfactant, urea and a salt of claim 4; and wherein the enzyme is a protease of claim 6 for the same reasons as set forth in the Office Action mailed on 12/19/2006.

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Applicant's arguments filed on 05/21/2007 have been fully considered, but are not found persuasive.

Applicant argues that there is support in the specification for the presently claimed method.

It is the Examiner's position that the specification's general method does not appear to describe structural features, in structural terms, that are common to the genus of all dust mite or pollen allergens. There is neither a representative number of species of dust mite or pollen allergens to describe the claimed genus, nor does the specification provide a description of structural features that are common to the dust mite or pollen allergens species. There is no structural description of dust mite or pollen allergens other than ones specifically exemplified (Cryj-2, Cryj-2 and dust mite extract Df allergens). Therefore, the specification's disclosure is inadequate to describe the claimed allergen inactivating method.

9. The following new ground of rejection is necessitated by the amendment filed on 05/21/2007.

Claim Rejections - 35 USC § 102

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10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 3-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishii et al. (PTO-892, Reference U).

Ishii et al. teaches an allergen inactivating method for dust mites mainly composed of protein allergens (crude dust mite extract) by maintaining the allergens under a condition in which the enzyme (trypsin and pronase) and a denaturing agent (NaCl solution) exist of claim 3; wherein the denaturing agent is salt (NaCl) of claim 4; and wherein the enzyme is a protease (trypsin and pronase) of claim 6 (In particular, page 263, right column second full paragraph to the end of the first paragraph on page 264, abstract).

The reference teachings anticipate the claimed invention

12. No claim is allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 2, 2007

Nora M. Rooney, M.S., J.D.

Patent Examiner

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